EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

July 12, 2019

Sent By Email
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Re: Document Access Request - *United States v. Elizabeth Holmes and Ramesh Balwani*, 18-CR-00258 EJD

Dear Messrs. Bostic, Coopersmith, and Downey:

This letter responds to the Court's June 28, 2019 order in the above-captioned action instructing the Centers for Medicare & Medicaid Services (CMS) to provide the parties with specific information regarding the documents the agency agrees to produce or objects to producing in response to the document requests made by the Government on behalf of Defendants.

In my previous letter to Mr. Bostic dated June 10, 2019, CMS agreed to provide documents in the agency's possession between September 1, 2013 and December 31, 2016[1] that are responsive to the six categories of documents requested and that are not protected by the attorney-client or work product privileges. The following is a summary of the steps CMS has taken to identify, collect, and review responsive documents.

CMS understands that the parties are currently negotiating a proposed Supplemental Protective Order that will govern CMS documents produced in this case and that Mr. Bostic is working to obtain a waiver from Theranos's assignee permitting CMS to disclose Theranos's trade secret and confidential commercial information to the parties in response to this document request. Once the Court enters the Supplemental Protective Order and the waiver is obtained, CMS will promptly

[1] Mr. Balwani's counsel previously agreed to narrow the time period relevant to Mr. Balwani's subpoena to CMS in *SEC v. Balwani*, Case No. 18-cv-01602-EJD to September 1, 2013 and December 31, 2016.

provide Mr. Bostic with 5,014 pages that fall within the following categories of external communications responsive to the document request as follows.

- Communications between the CMS Office of Communications and the media about Theranos, including communications between the agency and John Carreyrou or the Wall Street Journal. The CMS Office of Communications coordinates requests for information from members of the media and provides responses on behalf of the agency. These documents are responsive to Document Request No. 1.

- Communications between CMS (the Clinical Lab group and CCSQ Management) and Theranos. The CMS Division of Clinical Laboratory Management and Quality (the Clinical Lab group) is responsible for Clinical Laboratory Improvement Amendment (CLIA) programs. Two CMS employees from this group performed the 2015 CLIA survey of Theranos. The Clinical Lab group is part of the CMS Center for Clinical Standards and Quality (CCSQ) and some members of CCSQ management were involved with the Theranos matter after the 2015 survey was performed. These documents are responsive to Document Request No. 2.

- Communications between the Clinical Lab group and the American Association of Clinical Chemistry (AACC). These documents are responsive to Document Request No. 3. The CMS Clinical Lab group does not generally communicate with third parties about the CLIA compliance of particular laboratories. The agency conducted a limited search for communications between the CMS Clinical Lab group and LabCorp, Quest Diagnostics, or the AACC to confirm this practice. The search produced a few emails to or from AACC that are all form marketing emails or emails about attending the AACC Annual Scientific Meeting. These results confirm that CMS did not communicate with third parties about Theranos's lab compliance with CLIA and, therefore, the agency would not have additional documents responsive to Document Request No. 3.

- Documents from the California Department of Public Health's California Laboratory Field Services (CDPH) related to the federal 2013 Theranos CLIA Survey. These documents are responsive to Document Request No. 6. CDPH conducted a search and no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist. *See* Attachment A, Declaration of Donna McCallum, July 11, 2019.

Internal communications were redacted from the categories of documents listed above because they were originally reviewed for production in response to a subpoena in *SEC v. Balwani*, Case No. 18-cv-01602-EJD. CMS has produced these redacted documents to Mr. Balwani in the civil matter. Subsequent productions will include revised versions of materials where internal communications were previously redacted, but redactions made to protect information covered by the attorney-client or work product privileges will remain. CMS does not intend to withhold information that may be protected by the deliberative process privilege.

CMS also produced communications between the Clinical Lab group and the U.S. Food and Drug Administration (FDA) about Theranos to Mr. Balwani in *SEC v. Balwani*, Case No. 18-cv-01602-EJD. Once the Court enters the Supplemental Protective Order and the Theranos assignee provides a waiver, CMS will promptly produce those documents to Mr. Bostic. CMS also identified and reviewed additional CMS communications with the FDA about Theranos and is processing those communications for production. The estimated production date is the week of July 15, 2019. These documents are responsive to Document Request No. 4.

CMS has made significant efforts to identify, collect, review, and produce non-privileged internal email responsive to Document Request Nos. 1, 2, 4, and 6. These efforts are explained in detail below. Although CMS cannot control the amount of time it will take to load data into the Relativity review database, process the data so it is ready for review, or process the data for production, the agency has used its best efforts to provide an estimated time line. The time line assumes that a Supplemental Protective Order is entered by the Court and the Theranos assignee grants a waiver to allow CMS production of these documents.

- Internal email from employees in the CMS Office of Communications who dealt with media contacts about Theranos have already been collected and loaded into the review database. CMS is currently conducting a review for documents protected by the attorney-client and work product privileges. CMS estimates that these documents will be produced to Mr. Bostic by August 16, 2019. These documents are responsive to Document Request No. 1.

- Some internal email from employees in the Clinical Lab group and CCSQ Management have already been collected and loaded into the review database. CMS is currently conducting a review for documents protected by the attorney-client and work product privileges. CMS estimates that these documents will be produced to Mr. Bostic by August 16, 2019. These documents could be responsive to Document Request Nos. 1, 2, 4, and 6.

- In addition to the email previously collected, CMS has also started the process of collecting and identifying email from the Clinical Lab group, CCSQ Management, and FOIA personnel to provide a complete set of internal communications about Theranos between September 1, 2013 and December 31, 2016. CMS IT has almost completed collecting documents from these custodians and will work to identify the potentially responsive set of documents. The responsive set of documents will then need to be exported and shipped to the Relativity database staff. The CMS request to upload the data is then put into a queue and CMS has no control over how quickly the data is loaded. The average load time has recently been thirteen work days. Once the data is loaded, further processing is needed to get to the documents that CMS will need to review. The average time for data analysis and processing has recently been eight work days. CMS will not know the quantity of documents until this work is complete. CMS estimates that this data will be identified and loaded into the review database by August 23, 2016. Once the data is loaded, CMS will be better able to estimate how long it will take to review the documents for information protected by the attorney-client and work product privileges and produce them. CMS is exploring methods to potentially decrease the time it will take to produce these documents. CMS will provide a status update to the parties promptly after CMS knows the quantity of documents to review. These documents could be responsive to Document Request Nos. 1, 2, 4 and 6.

CMS does not have documents responsive to Request No. 5. While CMS interacts with and supports law enforcement, the agency does not serve a criminal law enforcement function and, therefore, it does not create or retain Reports of Investigation (ROIs) memorializing government communications with witnesses.

CMS is committed to working with you to produce documents responsive to your requests as detailed above. Please contact CMS counsel Lindsay Turner to discuss this matter further.

Sincerely,

Karen W. Dyer
Director
Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services

DECLARATION

I, Donna McCallum, hereby declare under penalty of perjury under the laws of the State of California that the following statements are true to the best of my knowledge and belief:

1. I am the Section Chief for the Clinical Laboratory Improvement Amendment (CLIA) Section for the California Department of Public Health's Laboratory Field Services (LFS). I have knowledge of the facts stated herein.
2. On June 3, 2019, I declared that LFS had in its custody specified Federal Centers for Medicare and Medicaid services (CMS) documents regarding the 2013 CLIA survey of Theranos.
3. In that declaration, I also stated that LFS had initiated an email search to verify that no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist and that LFS would confirm with CMS once the search inquiry is completed.
4. LFS has completed its email search inquiry and confirms that no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist.

I declare under penalty of perjury that the foregoing is true and correct.

Donna McCallum
Declarant Signature

7/11/2019
Date